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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,562	06/17/2005	Kristopher Buchanan	09138.0070	2677

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DAKO/FINNEGAN, HENDERSON, LLP  
901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER
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BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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08/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,562	<b>Applicant(s)</b> BUCHANAN ET AL.	
	<b>Examiner</b> NATHAN A. BOWERS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47, 75 and 90-113 is/are pending in the application.
- 4a) Of the above claim(s) 1-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75 and 90-113 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 75 and 90-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Richards (US 6296809).

With respect to claim 75, Richards discloses an automated sample processing system for processing a plurality of samples each on a respective carrier according to a processing protocol. Specifically, Richards indicates that samples are positioned on slides, which are in turn positioned on a carrier retention device in the form of a carousel (Figure 4:28). This is disclosed in column 6, lines 12-43. Column 6, lines 44-65 teaches that an active temperature regulation element comprising a resistive heaters, temperature sensors and a microprocessor controller is also provided to monitor the temperature of each sample slide during processing. Figure 9 indicates that each slide (37) is positioned just above a heating element (64) and a temperature sensor (68). This is further described in column 9, lines 4-66.

With respect to claims 90-95, Richards discloses the system in claim 75 wherein the processing system is capable of executing a variety of different techniques. Column 1, lines 18-47 and column 4, lines 5-15 state that the system can operate as either an automated immunohistochemistry processing system or a fluorescent in-situ hybridization processing

system. Column 3, lines 29-40 state that the apparatus is designed to accommodate DNA probe and/or antibody based staining procedures.

With respect to claims 96-98, Richards discloses the system in claim 95 wherein an active temperature reduction element is additionally provided. In column 7, lines 1-10 and column 14, lines 51-62, Richards teaches that cooling of the slide is accomplished through the use of Peltier coolers and fans.

With respect to claims 99-101, Richards discloses the system in claim 95 wherein the active temperature regulation element comprises a temperature ramp up and ramp down element, thus inducing regulated temperature increases and decreases within the sample. This is described in column 6, lines 44-65, column 9, lines 4-66, column 18, line 57 to column 19, line 28, and generally throughout the reference.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 2) Claims 102-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards (US 6296809) in view of Ammann (US 20050233370).

With respect to claims 102-108, Richards discloses the system set forth in the rejections above. Richards discloses at least one container having a reagent therein, as well as a sample carrier retention device. Sample temperature control elements are provided for regulating the temperature of the contents of the sample carrier retention device. Richards, however, does not expressly disclose that reagent temperature control elements are provided for regulating the temperature of reagents before they are applied to the sample.

Ammann discloses an automated system for processing a plurality of reaction receptacles each capable of holding and transporting a sample. Reaction receptacles are transported to an arrangement of incubators (Figure 4:600,602,604,606) where they are maintained at a predetermined temperature. Paragraphs [0130], [0332] and [0337]-[0369] state that reagents are stored in separate containers located within a reagent cooling bay (Figures 35-39). Ammann

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teaches that thermoelectric modules and fan units provide the desired cooling capacity, and are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

Richards and Ammann are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to equip Richard's reagent storage containers with cooling elements and a control system capable of regulating the temperature within the reagent storage containers. Reagents typical of microarray processing systems are known in the art to be temperature sensitive and susceptible to degradation if maintained under undesirable conditions. As evidenced by Ammann, it is well known in the art to keep reagents at cool temperatures during storage to ensure that they do not prematurely expire.

With respect to claims 109-113, Richards and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. In addition, Richards clearly indicates that a sample temperature control element is provided to ramp up and ramp down the temperature of the sample maintained within the carousel retention device during processing. This has been described in the rejections above.

### ***Response to Arguments***

Applicant's arguments filed 05 May 2008 have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) Richards regulates the temperature of the slides and not the sample. Richards' heating system does not bring the temperature of the sample to a set point and within a tolerance specified by a protocol.*

In response, please consider the following remarks.

The purpose of the temperature regulation system of Richards is to maintain each tissue sample at appropriate temperatures during different stages of a treatment protocol. The tissue samples are brought to a desired temperature, kept at a predetermined set point for a period of time, and then either heated or cooled to a different temperature. This is accomplished indirectly through the heating and cooling of the slides that support each tissue sample. It is true that the heating system of Richards directly heats the slides, but in doing so, the heating system also indirectly heats the samples located upon the slides. Richards is wholly concerned with the temperature of these tissue samples, and the heating of slides is merely the means by which this is accomplished. Measurements regarding slide temperature are only useful and relevant when they are used to estimate the corresponding tissue temperature. The Richards heating system serves to heat the tissue samples to a specified set point within a tolerance specified by a protocol by heating the plates to an associated temperature that will cause the tissue sample to reach the desired set point temperature.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/Nathan A Bowers/  
Examiner, Art Unit 1797